

Fees 2019 - Human medicinal products

Chapter 1 - Section 1 - Part 1 : Application for **MA/registration**, including line extensions (**national**)

		*
full/hybrid/bibliographic/biosimilar/fixe combination application MAD	31.855,39 €	566,00 €
generic/informed consent application MAD	27.725,57 €	566,00 €
application MAD or registration herbal medicine		
1) conform monograph	24.816,78 €	566,00 €
2) non-conform monograph	31.855,39 €	566,00 €

If Belgium is acting as RMS : **specific contribution** (see infra).

Contribution **per submitted dossier**, regardless of the number of MADs.

* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

Chapter 1 - Section 1 - Part 3 : Application for **MA/registration**, including line extensions (**DCP/MRP/RUP, BE=RMS**)

		*
full/hybrid/bibliographic/biosimilar/fixe combination application MAD	51.153,47 €	566,00 €
generic/informed consent application MAD	42.960,36 €	566,00 €
application MAD or registration herbal medicine		
1) conform monograph	31.671,16 €	566,00 €
2) non-conform monograph	51.153,47 €	566,00 €

Contribution **per submitted dossier**, regardless of the number of MADs.

* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

Chapter 1 - Section 1 - Part 2 : Application for **MA/registration**, including line extensions (**DCP/MRP/RUP, BE=CMS**)

		*
full/hybrid/bibliographic/biosimilar/fixe combination application MAD	10.838,86 €	566,00 €
generic/informed consent application MAD	9.324,08 €	566,00 €
application MAD or registration herbal medicine (regardless of conformity to a monograph)	9.324,08 €	566,00 €

Contribution **per submitted dossier**, regardless of the number of MADs.

* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

+ **Chapter 3**

a) Delayed closing of the dossier at request of the applicant **863,83 €**

Chapter 11 - Section 2

Application for reglementary advice concerning umbrella brand(s)

1.027,59 €

Chapter 1 - Section 2 - Part 1 : Renewal (national)

		*
Renewal	5.905,59 €	566,00 €
Renewal herbal medicine	7.343,61 €	566,00 €

If Belgium is acting as RMS : **specific contribution** (see infra).

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs.

* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

Chapter 1 - Section 2 - Part 3 : Renewal (MRP, BE = RMS)

		*
Renewal	12.035,33 €	566,00 €
Renewal herbal medicine	12.084,45 €	566,00 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs.

* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

Chapter 1 - Section 2 - Part 2 : Renewal (MRP, BE = CMS)

		*
Renewal	1.070,58 €	566,00 €
Renewal herbal medicine	1.242,53 €	566,00 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs.

* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

+ Chapter 3

a) Delayed closing of the dossier at request of the applicant

593,63 €

Chapter 1 - Section 3 - Part 1 : National variations

	*	**	***	****
a) 1) Type IA variations	551,67 €	551,67 € (+ 163,76 €/additional brand)		1 brand 551,67 €, ≥2 brands 566,00 €
a) 2) Type IA variations herbal medicine	458,53 €	458,53 € (+ 163,76 €/additional brand)		1 brand 458,53 €, ≥2 brands 566,00 €
For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 551,67 €, respectively 458,53 €, is also due.				
Part 4 administrative variations	439,08 €	439,08 € (+ 169,90 €/additional brand)		1 brand 439,08 €, ≥2 brands 535,29 €
b) 1) Type IB variations	1.202,61 €	1.202,61 € (+ 163,76 €/additional brand)		566,00 €
b) 1) Type IB variations herbal medicine	1.128,92 €	1.128,92 € (+ 163,76 €/additional brand)		566,00 €
c) Type II variations: analytical				
variations regarding the analytical part *****	7.257,63 €	7.257,63 € (+ 168,88 €/additional brand)		566,00 €
variations regarding the analytical part herbal medicine *****	9.201,26 €	9.201,26 € (+ 168,88 €/additional brand)		566,00 €
d) Type II variations: clinical				
All clinical changes	6.896,34 €	6.896,34 € (+ 593,63 €/additional brand)		566,00 €
All clinical changes herbal medicine	7.345,65 €	7.345,65 € (+ 593,63 €/additional brand)		566,00 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC	766,60 €		not applicable	566,00 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs (with the exception of **worksharings** and **horizontal groupings**).

* For **vertical groupings**, only the contribution of the variation with the highest workload (II > IB > IA) is due.

** For **horizontal groupings**, the contribution of 1 type IA/adm. variation + fixed amount per additional MP group (brand) is due.

*** For **worksharings**, the contribution of the concerned variation + fixed amount per additional MP group (brand) is due.

**** If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount. [No reimbursement is foreseen in case of refusal of **IA** or **administrative variation**. The administrative fee for IA or administrative variations is only applicable in case of technical inadmissibility of the request (regular or herbal medicine).]

***** In case **3 or more** separate **analytical type II files** for the same product are filed at the same moment, the price is capped to 3x the contribution related to the analytical part of a type II variation.

Chapter 1 - Section 3 - Part 2 : MRP-variations, BE = CMS

	*	**	***	****
a) 1) Type IA variations	357,20 €	357,20 € (+ 163,76 €/additional brand)		1 brand 357,20 €, 2 brands 520,96 €, ≥3 566,00 €
a) 2) Type IA variations herbal medicine	383,81 €	383,81 € (+ 163,76 €/additional brand)		1 brand 383,81 €, 2 brands 547,57 €, ≥3 566,00 €
For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 357,20 €, respectively 383,81 €, is also due.				
b) 1) Type IB variations	355,15 €	355,15 € (+ 163,76 €/additional brand)		1 brand 355,15 €, 2 brands 518,91 €, ≥3 566,00 €
b) 2) Type IB variations herbal medicine	313,19 €	313,19 € (+ 163,76 €/additional brand)		1 brand 313,19 €, 2 brands 476,95 €, ≥3 566,00 €
c) 1) Type II variations: analytical	528,13 €	528,13 € (+ 168,88 €/additional brand)		1 brand 528,13 €, ≥2 brands 566,00 €
c) 2) Type II variations: analytical herbal medicine	954,92 €	954,92 € (+ 168,88 €/additional brand)		566,00 €
d) 1) Type II variations: clinical	1.343,85 €	1.343,85 € (+ 593,63 €/additional brand)		566,00 €
d) 2) Type II variations: clinical herbal medicine	1.649,88 €	1.649,88 € (+ 593,63 €/additional brand)		566,00 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC	766,60 €		not applicable	566,00 €

If Belgium is acting as **RMS : specific contribution** (see infra).

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs (with the exception of **worksharings** and **horizontal groupings**).

* For **vertical groupings**, only the contribution of the variation with the highest workload (II > IB > IA) is due.

** For **horizontal groupings**, the contribution of 1 type IA/adm. variation + fixed amount per additional MP group (brand) is due.

*** For **worksharings**, the contribution of the concerned variation + fixed amount per additional MP group (brand) is due.

**** If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount. [No reimbursement is foreseen in case of refusal of **IA** or **administrative variation**. The administrative fee for IA or administrative variations is only applicable in case of technical inadmissibility of the request (regular or herbal medicine).]

Chapter 1 - Section 3 - Part 3 : MRP-variations, BE = RMS

	*	**	***	****
a) 1) Type IA variations	587,49 €	587,49 € (+ 163,76 €/additional brand)		566,00 €
a) 2) Type IA variations herbal medicine	587,49 €	587,49 € (+ 163,76 €/additional brand)		566,00 €
For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 587,49 € is also due.				
b) 1) Type IB variations	1.830,02 €	1.830,02 € (+ 163,76 €/additional brand)		566,00 €
b) 2) Type IB variations herbal medicine	1.930,32 €	1.930,32 € (+ 163,76 €/additional brand)		566,00 €
c) 1) Type II variations: analytical	6.022,27 €	6.022,27 € (+ 168,88 €/additional brand)		566,00 €
c) 2) Type II variations: analytical herbal medicine	6.022,27 €	6.022,27 € (+ 168,88 €/additional brand)		566,00 €
d) 1) Type II variations: clinical	10.140,83 €	10.140,83 € (+ 593,63 €/additional brand)		566,00 €
d) 2) Type II variations: clinical herbal medicine	10.140,83 €	10.140,83 € (+ 593,63 €/additional brand)		566,00 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC	766,60 €		not applicable	566,00 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs (with the exception of **worksharings** and **horizontal groupings**).

* For **vertical groupings**, only the contribution of the variation with the highest workload (II > IB > IA) is due.

** For **horizontal groupings**, the contribution of 1 type IA/adm. variation + fixed amount per additional MP group (brand) is due.

*** For **worksharings**, the contribution of the concerned variation + fixed amount per additional MP group (brand) is due.

**** If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount. [No reimbursement is foreseen in case of refusal of **IA** or **administrative variation**. The administrative fee for IA or administrative variations is only applicable in case of technical inadmissibility of the request (regular or herbal medicine).]

+ Chapter 3

a) Delayed closing of the dossier at request of the MAH

593,63 €

Chapter 6 : Parallel import

a) New application licence PI (RD* article 4) <u>or</u> modification licence PI (RD* article 7, §§ 2 and 3)	1.061,37 €/licence
b) Renewal licence PI (RD* article 7, §1)	1.061,37 €/licence
c) Modification licence PI (<u>except</u> RD* article 7, §§ 2 and 3)	911,94 €/licence

* **Royal Decree** relating to **parallel imports** of medicines for human use and to **parallel distribution** of medicines for human and veterinary use (**19/04/2001**)

Remarks:

CMS	=	Concerned Member State
DCP	=	DeCentralised Procedure
MAD	=	Marketing Authorisation Document
MAH	=	Marketing Authorisation Holder
MRP	=	Mutual Recognition Procedure
PIL	=	Patient Information Leaflet
RMS	=	Reference Member State
RUP	=	Repeat-Use Procedure
SmPC	=	Summary of Product Characteristics

All fees have to be paid in advance and the **proof of payment** is required (in part IA / module 1) before an application can be accepted.

Fees payable on account number: 679-0021942-20

IBAN-CODE: **BE28 6790 0219 4220**

Swift code: PCHQBEBB

"The attention is drawn to the fact that the current text is merely **informal**, and it is by no means certain that its current wordings and provisions correspond to the eventual **final text** that will be publically announced in the **Belgian Law Gazette**. The Federal Agency for Medicines and Health Products assumes no responsibility whatsoever as to such a lack of correspondence with the final text"